



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0660; FRL-8903-01-OCSPP]

Agency Information Collection Activities; Proposed Renewal Collection and Request for Comment; TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on the following Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB) “TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances (EPA ICR No. 1188.16 and OMB Control No. 2070-0038).” This ICR represents a renewal of an existing ICR that is currently approved through December 31, 2025. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number Docket ID No. EPA-HQ-OPPT-2021-0660, online at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Office of Program Support (Mail Code 7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-1206; email address: sleasman.katherine@epa.gov

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances

EPA ICR No.: 1188.16

OMB Control No.: 2070-0038

ICR Status: This ICR is currently approved through December 31, 2025. Under the PRA,

an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the *Federal Register* when approved, are displayed either by publication in the *Federal Register* or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: TSCA section 5 requires that any person who proposes to manufacture (which includes import) a “new chemical substance” (i.e., a chemical not listed on the TSCA section 8(b) Inventory) must provide a premanufacture notice (PMN) to EPA at least 90 days prior to commencing manufacture of that chemical and that EPA review such notice and take action as appropriate. Under TSCA, the term “chemical substance” includes microorganisms; the 90-day notice for microorganisms is a Microbial Commercial Activity Notice (MCAN).

Under TSCA section 5, EPA is authorized to determine that a use of a chemical substance is a significant new use and promulgate a significant new use rule (SNUR). In certain instances, persons may opt to pursue that significant new use, in which case they must submit a notice and undergo a review. For such circumstances, TSCA section 5 requires a significant new use notice (SNUN) from any person who proposes to manufacture or process a chemical for a use that is determined by EPA to be a “significant new use.”

TSCA section 5 requires EPA to make one of five possible determinations before the conclusion of its review of the submitted notices regarding risk to human health and the environment from the manufacture, processing, distribution in commerce, use and/or disposal of new chemical substances or significant new uses. EPA’s determination on a new chemical substance or new use will dictate how and to what extent the chemical’s manufacture, processing, distribution, use, and/or disposal may be restricted. If EPA fails to make a timely determination, fees may be refunded; however, nothing relieves EPA of its obligation to make a

determination. EPA requires that the submitter of a PMN or MCAN inform EPA when non-exempt commercial manufacture of the substance in question actually begins by submitting a Notice of Commencement; EPA would then add the new chemical substance to the TSCA section 8(b) Inventory.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and regulations that interpret TSCA section 12(b) appear at 40 CFR part 707 and the associated paperwork activities and burdens are approved under OMB Control No. 2070-0030, ICR entitled “Notification of Chemical Exports - TSCA Section 12(b),” identified by EPA ICR No. 0795.16.

Existing chemicals are chemicals that are already listed on the TSCA Inventory and therefore “existing chemical SNURs” are generally written to require notice for significant new uses of chemicals that are already in commerce.

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Form number(s): 7710-23, 7710-25, 7710-56 and 6300-7.

Respondents/affected entities: Entities potentially affected by this ICR include processors, e.g., entities identified by the North American Industrial Classification System (NAICS) codes 325, Chemicals and Allied Products Manufacturers, and 324, Petroleum Refining.

Respondent’s obligation to respond: Mandatory, 15 U.S.C 2604. 40 CFR parts 720, 721, 723 and 725.

Estimated number of potential respondents: 4,243.

Frequency of response: On occasion.

Total estimated average number of responses for each respondent: 1.

Total estimated burden: 128,367 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated costs: \$ 45,183,758 (per year), includes \$0 annualized capital investment or

maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is no change in the burden hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another *Federal Register* document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: May 2, 2025.

Nancy B. Beck,

Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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